

| Notice of Allowability | Application No. | Applicant(s) | |
|-------------------------------|----------------------|--------------|--|
| | 10/075,105 | LI ET AL. | |
| | Examiner | Art Unit | |
| | Celine X. Qian Ph.D. | 1636 | |

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to the amendment filed on 3/20/06.
2. The allowed claim(s) is/are 1-3,6-8,18,19,22 and 23.
3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some*
 - c) None
 of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. Notice of Informal Patent Application (PTO-152)
6. Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. Examiner's Amendment/Comment
8. Examiner's Statement of Reasons for Allowance
9. Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative Mr. James Krueger on 6/7/06.

The application has been amended as follows:

Claims 1: A bidirectional promoter complex comprising:
a modified enhancer region that includes [at least] two enhancer sequences; and [at least]
two core promoters, the core promoters being on either side of the modified enhancer
region in a divergent orientation; wherein the bidirectional promoter complex includes SEQ ID
NO:1.

Claim 2: The bidirectional promoter complex of claim 1 wherein the modified
enhancer includes [at least] two tandem oriented enhancer sequence having substantial sequence
identity.

Claims 4-5 are cancelled.

Claim 18: A vector comprising a bidirectional promoter complex, the bidirectional
promoter complex including a modified enhancer region and [at least] two core promoters, the
core promoters being on either side of the modified enhancer complex in a divergent orientation;
wherein the bidirectional promoter complex includes SEQ ID NO:1.

Claim 19: An [a] eukaryotic cell transfected with a vector, the vector comprising a bidirectional promoter complex, the bidirectional promoter complex including a modified enhancer region and [at least] two core promoters, the core promoters being on either side of the modified enhancer complex in a divergent orientation; wherein the bidirectional promoter complex includes SEQ ID NO:1.

Claim 22: A method for improving transcription efficiency of transgenes, the method comprising inserting the transgene into a vector, such that the transgene is operably linked to [the vector comprising] a bidirectional promoter complex, the bidirectional promoter complex including a modified enhancer region and [at least] two core promoters, the core promoters being on either side of the modified enhancer complex in a divergent orientation, [the bidirectional promoter complex being effective for improving transcriptional efficiency of the transgene;] wherein the bidirectional promoter complex includes SEQ ID NO:1, and wherein said bidirectional promoter complex improves transcription efficiency of said transgene.

Claim 23: A method for producing one or more polypeptides encoded by a transgene, the method comprising inserting [a] said transgene into a vector, [the vector comprising] wherein the transgene is operably linked to a bidirectional promoter complex, the bidirectional promoter complex including a modified enhancer region and [at least] two core promoters, the core promoters being on either side of the modified enhancer complex in a divergent orientation, [the bidirectional promoter being effective for improving transcriptional efficiency of the transgene;] wherein the bidirectional promoter complex includes SEQ ID NO:1; introducing said vector into a host cell; culturing said host cell under appropriate condition so that one or more polypeptide encoded by the transgene is produced.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CXQ

CELINE QIAN, PH.D.
PRIMARY EXAMINER

